

Appl. No. 09/848,948  
Reply to Office action of February 8, 2005  
Response dated May 9, 2005

### **REMARKS**

#### **I. Introduction**

This paper is submitted in response to the Office Action mailed January 13, 2005 for the above-identified patent application. A one (1) month extension to the time for responding to the Official Action is respectfully requested. Claims 1-32 are pending in the application. Claims 6-13 and 19-32 have been withdrawn from consideration. Claims 1-5 and 14-18 have been rejected.

Independent claim 14 has been amended to include the recitations of now canceled claim 15. Independent claims 1 and 14 have also been amended to recite that at least one S100 protein is selected from the group consisting of S100-A7 and S100-A8. No new matter has been added.

#### **II. The Rejections Under 35 U.S.C. §112 ¶1 Should Be Withdrawn**

The Examiner has rejected claim 14 under 35 U.S.C. §112 ¶1, as failing to comply with the written description requirement. The Examiner states that the specification does reasonably convey to one skilled in the art an antibody that would bind to S100 protein such that the resulting complex can be detected. (*See Official Action* mailed May 11, 2004 ¶6). Applicants have amended claim 14 to include the recitations of now canceled claim 15. Amended claim 14 now recites that the component for detecting the S100 protein is an anti-S100 antibody. Therefore, reconsideration and withdrawal of the rejection of claim 14 under 35 U.S.C. §112 ¶1 is respectfully requested.

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**III. The Rejections Under 35 U.S.C. §102 Should Be Withdrawn**

Claims 1, 2, 4, 5, 14 and 15 have been rejected under 35 U.S.C. § 102(a) as being unpatentable in view of International Publication No. WO 98/35985 A1 to Hanash ("Hanash"). Applicants have amended independent claims 1 and 14 to recite diagnosis of cancer in a subject comprising detecting at least one S100 protein selected from the group consisting of S100-A7 and S100-A8.

The Examiner alleges that Hanash teaches an antibody that binds S100-A9 and can be used to determine the amount of S100-A9 in the serum of a subject having a lung tumor. However, the antibody disclosed in Hanash binds an epitope formed by heterodimerization to determine the amount of S100-A9 in a subject having cancer. But there is no disclosure that this antibody may be used to determine an elevation in either S100-A8 or S100-A7 in the serum of a subject having lung cancer. Indeed, because of the specificity of the antibody disclosed by Hanash, one skilled in the art would not expect that elevated levels of S100-A8 or S100-A7 can be detected in the serum of lung cancer patients. Consequently, Hanash does not disclose diagnosis of cancer by detection of S100-A7 or S100-A8 protein as recited in independent claims 1 and 14. As claims 2, 4 and 5 depend from independent claim 1, these dependent claims are patentable for at least the same reasons. Therefore, reconsideration and withdrawal of the rejection of claims 1, 2, 4, 5 and 14 under 35 U.S.C. § 102(a) is respectfully requested.

Claim 14 has been rejected under 35 U.S.C. § 102(b) as being unpatentable in view of BIO-RAD Life Sciences Research Products Price List Q (March 1991) ("BIO-

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RAD"). The Examiner alleges that BIO-RAD teaches a kit comprising a component for detecting the presence of A100-A7, S100-A8 or S100-A9 in a biological sample.

To render a claim anticipated under 35 U.S.C. § 102, a single prior art reference must disclose each and every element of the claim in exactly the same way. See *Lindeman Maschinenfabrik v. Am Hoist and Derrick*, 730 F.2d 1452, 1458 (Fed. Cir. 1984) (emphasis added). Independent claim 14 as presently amended recites, in part, a kit for diagnosis of cancer in a subject comprising a component for detecting the presence S100 protein in a biological sample. In contrast, BIO-RAD discloses the detection of bound antibodies using only direct labeling or labeled secondary antibodies and reagents for the staining of proteins. The only example of protein detection in human serum relates to transferrin. Therefore, BIO-RAD does not disclose *a component for detecting the presence of S100 protein* as recited in independent claim 14. As a result, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of anticipation with respect to claim 14.

Claims 14 and 15 have been rejected under 35 U.S.C. § 102(a) as being unpatentable in view of Newton *et al.* J. IMMUNOL. 160:1427-35 (1998) ("Newton"). The Examiner states that Applicant's argument that Newton fails to disclose a kit for diagnosis of cancer is not persuasive because the preamble is not a claim limitation.

Although the preamble of a claim is not necessarily a limitation, it will be considered a claim limitation if it is necessary to give meaning to what the inventors actually invented and intended to encompass by the claim. See *Catalina Mktg. Int'l v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002). The problem solved by the

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present invention, and intended to be encompassed by the claims, are methods of diagnosis of cancer. Thus, independent claim 14 is specifically directed to a kit for diagnosis of cancer. Moreover, independent claim 14 has been amended to recite that the presence of S100 protein in the subject's sample as compared to a control sample is an indicator of a subject with cancer. Since Newton does not disclose a kit for diagnosis of cancer, applicants respectfully submit that the claims are not anticipated. As stated above, independent claim 14 has been amended to include the recitations of now canceled claim 15. Therefore, reconsideration and withdrawal of the rejection of claim 14 under 35 U.S.C. § 102(a) is respectfully requested.

#### **IV. The Rejections Under 35 U.S.C. §103 Should Be Withdrawn**

Claims 3 and 16-18 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Hanash further in view of BIO-RAD. The Examiner alleges that at the time of the invention it was routine and conventional in the art to detect and/or quantify a protein by immunoprecipitation.

To establish obviousness of a claimed invention all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981 (CCPA 1974). Independent claims 1 and 14 have been amended to recite diagnosis of cancer in a subject comprising detecting at least one S100 protein selected from the group consisting of S100-A7 and S100-A8. As stated above, Hanash fails to teach or suggest all the recitations of independent claims 1 and 14. In particular, there is no disclosure of an antibody that may be used to determine an elevation in either S100-A8 or S100-A7 in the serum of a subject having cancer. Moreover, because of the specificity of antibodies, one

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skilled in the art would not expect that elevated levels of S100-A8 or S100-A7 could be detected in the serum of cancer patients. In addition, BIO-RAD does not teach or suggest the missing recitations of independent claims 1 and 14. As claims 3 and 16-18 depend from independent claims 1 and 14, these dependent claims are patentable for at least the same reasons.

Even assuming, *arguendo*, that the cited references could be modified to obtain the presently claimed invention, the mere fact that references might be modified is not enough to constitute obviousness unless the prior art also suggests the desirability of the modification. Moreover, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art, and not be based on the Applicant's disclosure. *See In re Vaack*, 947 F.2d 488 (Fed. Cir. 1991). Neither Hanash nor BIO-RAD teach or suggest diagnosis of cancer in a subject comprising detecting at least one S100 protein selected from the group consisting of S100-A7 and S100-A8 as recited in amended independent claims 1 and 14. Furthermore, neither reference suggests the desirability of modifications to obtain a method or kit for the diagnosis of cancer as recited in the present invention.

Therefore, reconsideration and withdrawal of the rejection of claims 3 and 16-18 as obvious in view of Hanash further in view of BIO-RAD is respectfully requested.

**V. Double Patenting Rejections**

Claims 1, 2, 4 and 5 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-15 of copending Application No. 10/461,424. In addition, claims 3 and 14-18 have been rejected under

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the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-15 of copending Application No. 10/461,424 further in view of BIO-RAD.


Applicants will file a terminal disclaimer, in compliance with 37 C.F.R. 1.321(c), to overcome the rejection based on the judicially created doctrine of double patenting upon notification of allowable claims.

#### VI. Conclusion

In view of the foregoing remarks, reconsideration and allowance of pending claims 1-5 and 14-18 is respectfully requested.

A one (1) month extension to the time for responding to the Official Action is respectfully requested. Payment of the extension fee is to be made according to the Credit Card Payment Form attached herewith. Applicants believe that no additional fees are required in connection with this response. However, if additional fees are required, the Commissioner is hereby authorized to charge any additional payment, or credit any overpayment, to Deposit Account No. 01-2300.

Respectfully submitted,

  
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**FEE CALCULATION**

Any additional fee required has been calculated as follows:

       If checked, "Small Entity" status is claimed.

	(Column 1)	(Column 2)	(Column 3)	SMALL ENTITY			LARGE ENTITY	
	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NO. PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	ADD'L. FEE	OR	RATE	ADD'L. FEE
TOTAL CLAIMS	31 MINUS	32	= -0-	x \$25	\$-0-		x \$50	\$-0-
INDEP CLAIMS	6 MINUS	6	= -0-	x \$100	\$-0-		x \$200	\$-0-
<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEP. CLAIM				+ \$180	\$-0-	OR	+ \$360	\$-0-
					\$-0-			\$-0-

The U.S. Patent and Trademark Office is hereby authorized to charge and deficiency or credit any overpayment of fees associated with this communication to Deposit Account No. 01-2300 referencing docket number 108140.00014.